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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,590	08/14/2001	John R. Reynolds	41530/28295	3647

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,590

Applicant(s)

REYNOLDS ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) _____
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 54-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Pickett et al.

Pickett et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad with an overlayer and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually, (Fig. 1A and entire reference).

3. Claims 54-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr, et al. (USPN 6,527,762).

Santini Jr, et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad with an overlayer and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication

with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually, (Fig. 1A and Columns 1, 2, 4-8, 14-16, 23, 24 and entire reference).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickett et al. (USPN 6,132,752) and further in view of Reynolds et al. (Publication).

Pickett et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually, (Fig. 1A and entire reference), but fails to disclose a the overlayer being used for preventing spontaneous release.

Reynolds et al. discloses the use of a bilayer strategy to impede spontaneous release of a drug and thus provide greater controlled delivery (last paragraph).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the invention of Pickett et al with the teachings of Reynolds et al. because Reynolds et al. teaches the advantage of using a bilayer strategy wherein the

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first layer is a drug and the second layer is a overlayer that impedes the release of the drug. Therefore, one of ordinary skill would use an overlayer in Pickett et al. to better control the drug being released for treatment.

6. Claims 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (USPN 4585652).

Miller et al. discloses an electrode drug delivery system comprising an electroactive polymer having at least one electrically addressable release pad and at least one electrode system containing a drug releasable therefrom upon application of a potential to said electrode which is in electrical communication with at least one independently electrically addressable release pad and wherein the medication can be released by bursts or gradually (Fig. 1, 2 and entire reference, Column 2, lines 50-68, Column 6, lines 59-65)

At the time of the invention it would have been obvious for one of ordinary skill in to modify Miller et al. to have two electrodes because it is well known that duplicating the components of a prior art device is a design consideration within the skill of the art.

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), and therefore, a mere modification that would have been obvious.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 54-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-63 of copending Application No. 09/929197. Although the conflicting claims are not identical, they are not patentably distinct from each other because having an electroactive polymer and the use of burst electrodes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

9. Applicant's arguments with respect to claims 54-63 have been considered but are moot in view of the new ground(s) of rejection.

10. The 103 rejection on claims 61-63 in view of Miller et al. (USPN 4585652) have been withdrawn. With regards to claims 54-60, the examiner holds the position that by duplicating the electrode on the release pad, Miller et al. would teach the claimed invention. The reason for withdrawing the method claims, is that there are no teachings in Miller et al. that would support the ability to produce a first release and then a second release, but with the apparatus Miller et al. teaches the ability to use either burst or gradual release of the drug, and thus by duplicating the electrode one of ordinary skill

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would have the ability to either use burst or gradual release of the drug as taught in the specification of Miller et al.

11. With regards to the overlayer limitation, Miller et al. discloses the use of coating the electrode, which the examiner is interpreting as the overlayer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto
Art Unit 3763
September 20, 2004



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